

REMARKS

Claims 1-24 are pending in the present application. Claims 13-24 have been withdrawn from consideration. Claims 1-12 and have been examined on their merits. By this amendment, claims 13 and 14 have been added. The Applicant believes that the new claim 13-14 are fully supported in the specification and do not represent new matter.

Claim Rejections

The Rejection Under 35 U.S.C. §112

Claims 10-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant believes that the present amendment overcomes this rejection.

As suggested by the Examiner, claim 11 has been amended to include "consisting" after "group" in line 2 so as more clearly to indicate the Markush Group. Also, in claim 10, line 3, the typographical error "cellulose" has been replaced with "cellulase" as the Applicant intended to designate the enzyme rather than the carbohydrate as part of the Markush Group of enzymes. In view of the amendments to claims 10 and 11, the rejection under 35 USC §112, second paragraph, should be reconsidered and withdrawn.

The rejection Under 35 U.S.C. §102/103

Claims 1-3, 8-9 and 11-12 are rejected under 35 U.S.C § 102 (a, e) as anticipated by Li *et al.* (U.S. Pat. No. 6,376,508). Applicant's claims as amended are directed to a method of treating SMA with the combination of three active ingredients, namely (1) vitamin C; (2) flavenoids, and (3) pectin. Li *et al.* teach that sodium butyrate and other butyrates (i.e., butyric acid; and butyrate salts

such as arginine butyrate) are useful for the treatment of SMA (col. 4, line 66 to col. 5 line 2) and that anti-microbial agents, including phenol and ascorbic acid (col. 5, line 59), may be used with a carrier (i.e., water, physiological saline, etc.; col. 5 lines 50-55) in a formulation for injection or intravenous administration (col. 5, lines 48-59). Although Li *et al.* does disclose that ascorbic acid (vitamin C) may be present as an anti-microbial agent in a formulation for treatment of Spinal Muscular Atrophy, this art clearly does not teach the use of pectin or flavenoids in combination with vitamin C for treatment of Spinal Muscular Atrophy. The present invention teaches the use of phenolic “flavonoids/bioflavonoids” (phenolic glycosides; c.f., specification page 19, line 11 et. seq.) that is quite different from Li *et al.*’s use of “phenol” (phenolic acid) as an antimicrobial. Also, the mention by Li *et al.* of the use of “orange flavoring” (col. 6, line 18) is unclear (i.e., a variety of synthetic and natural products are used as orange flavoring), but it is not the “citrus pectin” or “flavonoids” taught by Applicant. Certain citrus flavenoids/bioflavonoids may conveniently be extracted from the rind of citrus fruits (c.f., specification page 20, line 19). The present invention as currently claimed is not anticipated by Li *et al.* The rejection under 35 U.S.C § 102 should properly be reconsidered and withdrawn.

As noted above, Li *et al.* does not disclose essential ingredients of the claimed invention (i.e., pectin and flavenoids). Also, in view of the great medical difficulty of treating patients with SMA, there is not any suggestion or motivation in Li *et al.* or in the knowledge of one of ordinary skill in the art to modify Li *et al.* with any reasonable expectation of success to arrive at Applicant’s claimed invention. The rejection under 35 U.S.C. §103(a) in view of Li *et al.* should be reconsidered and withdrawn.

The rejection Under 35 U.S.C. §103(a)

Claims 4-7 and 10 are rejected under 35 U.S.C. §103(a) as being obvious and unpatentable over by Li *et al.* (U.S. Pat. No. 6,376,508) in view of Izvekova

et al. (U.S. Pat. No. 6,156,320) and Wu (U.S. Pat. No. 5,595,743). Izvekova *et al.* is directed toward the treatment of disease or conditions that involve opportunistic or pathogenic microorganism(s) by use of cultured bacteria (i.e., *Lactobacillus spp.*). Izvekova *et al.* disclose fermented milk products that may (i) contain “additives”, including apple pectin as a thickening agent (col. 4, line 57) and (ii) vitamin C as a vitamin/antioxidant (col. 5, line 36); and (iii) may be used for treating diseases (including general mention of “atrophy and dystrophy”, col. 5., lines 64-65) or conditions that are caused by or contributed by opportunistic or pathogenic microorganisms (col. 5, line 47-66). While fermented milk products may help some cases of atrophy and dystrophy in children, it should be noted that Spinal Muscular Atrophy is one of 40 types of muscular dystrophy. Izvekova *et al.* does not teach treatment of children with Spinal Muscular Atrophy or even mention the flavenoids of Applicant’s invention. As discussed hereinabove, Li *et al.* does disclose that ascorbic acid (vitamin C) may be present as an anti-microbial agent in a formulation for treatment of Spinal Muscular Atrophy. As the Examiner correctly notes, Wu (U.S. Pat. No. 5,595,743) teaches medicinal treatment that included enzymes, including amylase. In the cited art there is no mention of the use of the flavonoids of the invention, let alone use of flavonoid in concert with vitamin C and pectin as active ingredients for treatment of SMA.

A *prima facie* case of obviousness must have some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings, with a reasonable expectation of success; and the art reference or combined references much teach or suggest all the claim limitations. There is no teaching or suggestions of the limitations of the claims as currently amended. The combination of Li *et al.*, Izvekova *et al.* and Wu does not even identify the use of flavenoid, one of the key elements of Applicant’s main independent claim 1. The “gap” between Applicant’s invention and the art cannot be filled by reasonably modifying any reference or filled by general knowledge of

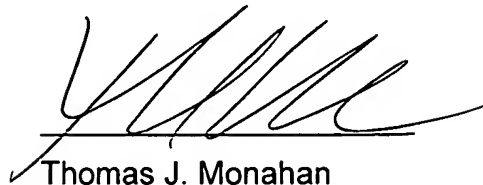
those of ordinary skill in the art. There is no teaching or contemplation of the use of flavenoid(s) in concert with vitamin C and pectin for the treatment of SMA. There is not the faintest motivation to fill the gap between the art and the present invention. The cited art clearly does not suggest, provide motivation for, or arrive at Applicant's invention. Accordingly, the Applicant requests that the rejection under 35 U.S.C. §103(a), as applied to pending claims, be appropriately withdrawn. Should Applicant's main independent claim 1 as amended be found allowable, so also should claims dependent thereon be allowed.

The Applicant submits that amended claims 1- 3, 6-7, and 9-12 and new claims 13-14 further describe and clarify the invention and define over the prior art. The amended and new claims under examination are offered to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In view of the above remarks responsive to the subject Office Action, the applicant believes that the rejections under 35 U.S.C. § 112, second paragraph, 35 U.S.C. 102 (a, e) and 35 U.S.C. 103 (a) should be reconsidered and withdrawn. The claims as amended are believed responsive to this rejection. The newly added dependent claims also represent patentable subject matter. Reconsideration and allowance, being in order, are earnestly solicited. Should there be further issues, the undersigned would welcome a telephone call to facilitate their resolution

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'T. Monahan', written over a horizontal line.

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